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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,117	10/16/2003	Vincent P. Stanton JR.	11926-006002	7321

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EXAMINER	
SWITZER, JULIET CAROLINE	
ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 06/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/687,117	STANTON, VINCENT P.	
	Examiner	Art Unit	
	Juliet C. Switzer	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 17-23 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 17-23 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 8/04; 10/03.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The preliminary amendment filed 10/16/03 has been entered. Claims 1-16 were canceled, claims 17-23 were added and are examined in this office action.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 17, 18, 19, and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Vande Woude et al. (US 5645988).

Regarding claim 17, Vande Woude et al. teach a method comprising steps of (a) analyzing a plurality of cell lines derived from unrelated individuals to determine the genotype of the candidate gene in each of the plurality of cell lines, (b) determining the drug response phenotype of each cell line in the plurality of call lines and (c) identifying the drug response phenotype as a drug response phenotype that varies among cell lines as a consequence of genetic variation in the candidate gene if the drug response phenotype correlates with the genotype of the candidate gene. Namely, regarding (a), Vande Woude et al. teach analyzing the status of the ras family of oncogenes contained within sixty human tumor cell lines (Example 1, Col. 34, especially beginning at line 45). Vande Woude et al. teach analyzing the genes within each cell line to determine genotypes (Col. 37, beginning at line 15, and Table 3). Regarding instant step (b), Vande Woude et al. then continue by identifying drugs which inhibit the growth of cancer

cells containing activated ras genes, thus determining the drug response phenotype of the cell lines (Example 2), and then, as in instant step (c), identifying a correlation between drug sensitivity (drug response phenotype) and genotype of cell lines in the candidate genes (Col. 39, lines 15-18). Vande Woude et al. further exemplify a method for screening additional drugs (Example 3, beginning in Col. 32), where six cell lines were cultured in vitro and tested against twenty different drugs. The genotypes of the ras genes win these cell lines was determined (Col. 43, lines 5-15), the drug response phenotype was observed (Col. 43, lines 16-39), and the response was correlated with the cell line and thus the cell line genotype (Col. 43, lines 16-45). Thus, Vande Woude et al. teach a method which meets the limitations of the instant claim. Further, regarding claim 18, Vande Woude et al. considered sixty cell lines, which is "at least 20 cell lines (Example 1). Regarding claim 19, the drug response phenotypes were measured in the presence of the drugs, as the phenotype was differential growth inhibition of the cell lines in the presence of the drugs (Col. 39, lines 8-10 and Example 3). Regarding claim 23, the response is drug sensitivity (Col. 39, lines 8-18 and Example 3).

4. Claims 17, 19, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Quadri et al. (Immunology Letters 61 (1998)25-31).

Regarding claim 17, Quadri et al. teach a method comprising steps of (a) analyzing a plurality of cell lines derived from unrelated individuals to determine the genotype of the candidate gene in each of the plurality of cell lines, (b) determining the drug response phenotype of each cell line in the plurality of call lines and (c) identifying the drug response phenotype as a drug response phenotype that varies among cell lines as a consequence of genetic variation in the candidate gene if the drug response phenotype correlates with the genotype of the candidate

gene. Namely, regarding (a), Quadri et al. teach analysis of thirteen total T1 and tumor cell lines by hybridizing oligonucleotide probes to determine the genotype of TAP genes TAP1 and TAP2 (section 2.6, "TAP typing", Table 1). Regarding instant step (b), Quadri et al. teach analysis of the cell lines for a drug response phenotype, analyzing the uptake of substrate peptides (section 2.4, "Peptide translocation"), and then, as in instant step (c), identifying a correlation between uptake (drug response phenotype) and genotype of cell lines in the candidate genes (section 3.1). Thus, Quadri et al. teach a method which meets the limitations of the instant claim. Regarding claim 19, the drug response phenotypes were measured in the presence of the drugs, as the phenotype was uptake of the administered drugs (the test peptides) (section 2.4). Regarding claim 20, the response is drug uptake (section 2.4).

5. Claims 17, 19, 21, and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Veronese et al. (Biochem J. (1993) 289, 533-538).

Regarding claim 17, Veronese et al. teach a method comprising steps of (a) analyzing a plurality of cell lines derived from unrelated individuals to determine the genotype of the candidate gene in each of the plurality of cell lines, (b) determining the drug response phenotype of each cell line in the plurality of call lines and (c) identifying the drug response phenotype as a drug response phenotype that varies among cell lines as a consequence of genetic variation in the candidate gene if the drug response phenotype correlates with the genotype of the candidate gene. Namely, regarding (a), Veronese et al. teach analysis cDNA fragments which are subsequently transfected into COS-7 cells to produce cell lines with different genotypes (p. 534, first column). These are considered to be cell lines derived from "unrelated individuals" because the cells in the lines cease to have common genetic content when they are transfected with the

vectors comprising different allelic variants of human liver cytochrome P-450 isoenzymes. The subsequently produced cells in the cultures, therefore, are derived from unrelated individual cells. Veronese et al. analyzed the genetic content of these cell lines by analyzing the genetic content of the vectors that were introduced into the cells. Regarding instant step (b), Veronese et al. teach analysis of the cell lines for a drug response phenotype, analyzing the ability of the cell lines to catalyze tolbutamide and phenytoin hydroxylation (p.534, 2nd column), and then, as in instant step (c), identifying a correlation between hydroxylation (drug response phenotype) and genotype of cell lines in the candidate genes (p. 535, 2nd column, and Table 2). Thus, Veronese et al. teach a method which meets the limitations of the instant claim. Regarding claim 19, the drug response phenotypes were measured in the presence of the drugs, as they do not teach the removal of the drugs prior to analysis. Regarding claim 21, the response is drug biotransformation, namely hydroxylation which an oxidation (throughout).

6. Claims 17, 19, 21, and 22 are rejected under 35 U.S.C. 102(a) and 35 U.S.C. 102(b) as being anticipated by Gill et al. (Pharmacogenetics February 1999, Vol. 9, pages 43-53).

This reference is being applied under 102(b) because the rejected claims do not appear to have support in the provisional application. The provisional application discusses assays similar to those instantly claimed at pages 39, 125 and in claim 150 as set forth in the provisional application, however, none of these appear to support method wherein the cell lines are from "unrelated" individuals. Further, these sections do not appear to discuss the different listed biotransformations of claim 22. This reference is thus a 102(b) date type reference against the pending claims. In the event that applicant is able to establish priority to the provisional

application for the claimed invention (by specifically pointing out how each claim in it's entirety is supported in the provisional application), the reference remains available under 102(a), and thus, in the interest of compact prosecution both rejections are set forth herein.

Regarding claim 17, Gill et al. teach a method comprising steps of (a) analyzing a plurality of cell lines derived from unrelated individuals to determine the genotype of the candidate gene in each of the plurality of cell lines, (b) determining the drug response phenotype of each cell line in the plurality of call lines and (c) identifying the drug response phenotype as a drug response phenotype that varies among cell lines as a consequence of genetic variation in the candidate gene if the drug response phenotype correlates with the genotype of the candidate gene. Namely, regarding (a), Gill et al. teach analysis genomic DNA from human liver cell samples by genotyping of CYP2C9*2 or CYP2C9*3 mutations. These cell samples are considered "cell lines derived from unrelated individuals" because the cell samples themselves are a series or "line" of cells produced (albeit in vivo) from different individuals (p. 45). Further, Gill et al. obtain samples from expressed cDNA cell lines which are also cell lines from different individuals provided by Gentest (p. 44). These were also "analyzed" to determine their genotype as they were ordered according to their genotype (p. 44). Regarding instant step (b), Gill et al. teach analysis of the cell lines for a drug response phenotype, analyzing the ability of the cell lines to catalyze sulphamethoxazole and tolbutamide hydroxylation (p.45-46), and then, as in instant step (c), identifying a correlation between hydroxylation (drug response phenotype) and genotype of cell lines in the candidate genes (p. 46, table 1). Thus, Gill et al. teach a method which meets the limitations of the instant claim. Regarding claim 19, the drug response

phenotypes were measured in the presence of the drugs. Regarding claim 21, the response is drug biotransformation, namely hydroxylation which an oxidation (throughout).

Conclusion

7. No claim is allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C Switzer whose telephone number is (571) 272-0753. The examiner can normally be reached on Monday, Tuesday, or Thursday, from 9:00 AM until 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached by calling (571) 272-0735.

The fax phone numbers for the organization where this application or proceeding is assigned are (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-0507.

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problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

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Juliet C. Switzer
Primary Examiner
Art Unit 1634

June 22, 2006